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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,706	07/28/2003	Peter Schreier	CS7861/LeA 36,055	5287
34469	7590	01/05/2006	EXAMINER	
BAYER CROPSCIENCE LP Patent Department 100 BAYER ROAD PITTSBURGH, PA 15205-9741			MEAH, MOHAMMAD Y	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 01/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/628,706	Applicant(s) SCHREIER ET AL.	
	Examiner Mohammad Meah	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 4-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 16 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>03/25/08</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

With preliminary amendment of this application, the applicant, on date 10/14/2005 elected with traverse Group I (claims 1-3 and 16-17) for further examination.

Election/Restriction

During preliminary amendment of this application, the applicant, on date 10/20/2005 elected without traverse Group I (claims 1-3 and 16-17) drawn to methods of identification fungicide for examination. Groups II-V (claims 4-15) of election/restriction-office action of date 08/23/2005 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected Groups.

Priority

Acknowledgement is made of applicant's claimed foreign priority date based on application filing date of 08/01/2002 in Germany, of application # Germany 10235129.5.

Claim Objections

Claims 16 and 17 are objected to as being in improper form because of the following informalities:

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Claims 16 and 17 are objected under 37 CFR 1.75(c) as being in improper form because they are improperly multiply dependent, See MPEP § 608.01(n). A multiply dependent claim can not depend from another multiply dependent claim and should refer to other claims in the alternative only. Accordingly, claims 16 and 17 have not been further treated on the merits.

Claim 2, line 1, "wherein" should be inserted before " fungicidal action".

Claim Rejections

35 U.S.C 112

Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-3 rejected under 35 U.S.C. 112, second paragraph, as being indefinite as explained below :

Claim 1 "a nucleic acid with the biological activity of ribose-5-phosphate isomerase" is unclear as nucleic acids do not have enzymatic activity.

Claim 2 is incomplete - merely contacting a fungus with a compound does not identify fungicidal activity> In order to identify fungicidal activity a step of comparing

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growth or amount of the fungus in the presence and absence of the compound is needed.

Claim 3 is incomplete as lacking any steps- how are the members of the list used?

Claims 1-3 are rejected under U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor at the time the application was filed, had possession of the claimed invention.

These claims are directed to methods of identifying chemical compounds as fungicide using a genus of ribose-5-phosphate isomerases. The specification fails to describe in any fashion the physical and/or chemical properties of the claimed class of ribose-5-phosphate isomerases and teach the structure of only a single representative species thereof. Moreover the specification fails to describe any additional species of ribose-5-phosphate isomerase by any identifying characteristics other than the functionality of ribose-5-phosphate isomerase activity. Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of screening for inhibitor of ribose-5-phosphate isomerase of SEQ ID NO:2 and then identifying the chemical compound to use as fungicide does not reasonably provide enablement for methods of identification a chemical compound as fungicide that inhibits any ribose-5-phosphate isomerase. These claims broadly recite the use of **any** ribose-5-phosphate isomerase.

Applicants claim a method for identifying chemical agents with antifungal activity comprising using a genus of ribose-5-phosphate isomerases to screen for compounds that inhibit ribose-5-phosphate isomerases activity and determining whether the inhibitor of ribose-5-phosphate isomerases preferentially act as fungicide.

The specification, while being enabling for use of the ribose-5-phosphate isomerase of SEQ ID NO:2 does not reasonably provide enablement for **any** ribose-5-phosphate isomerases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Claims 1-3 are so broad as to encompass methods of identifying fungicides using any ribose-5-phosphate isomerase. The scope of the claims is not commensurate with

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the enablement provided by the disclosure with regard to the extremely large number of ribose-5-phosphate isomerases broadly used by the methods of the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the nucleotide and encoded amino acid sequence of only one ribose-5-phosphate isomerase.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass methods of using any ribose-5-phosphate isomerases because the specification does not establish: (A) regions of the protein structure which may be

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modified without effecting ribose-5-phosphate isomerases activity; (B) the general tolerance of ribose-5-phosphate isomerases to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any ribose-5-phosphate isomerases residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including use of ribose-5-phosphate isomerases with an enormous number of amino acid modifications of the ribose-5-phosphate isomerase of SEQ ID NO: 2. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of ribose-5-phosphate isomerases for using the claimed methods having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

CLAIM Rejection - 35 U.S.C 103a

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3 are rejected under 35 U.S.C. 103(a) by Selitrennikoff et al. (US Pat 6743598), and Monk et al (Crit Rev. Microbiol 1994, 20, 209-223) in view of Lohrke et al. (Molec. Plant-Microbe interc. 11 April 2002, 15, 817-825) and Sorensen et al. (J. Bacteriol. Feb 1996, 1003-1011).

Fungal growth requires most of the enzymes in pentose phosphate metabolism. Phosphoribose isomerase ((Lohrke et al., Molec. Plant-Microbe interc. 11 April 2002, 15, 817-825) and (Sorensen et al., J. Bacteriol. Feb 1996, 1003-1011)), phosphoglucose isomerase (Selitrennikoff et al. US Pat 6743598) and ATPases (Monk et al., Crit Rev. Microbiol 1994, 20, 209-223) are each taught by the art to be necessary for fungal growth.

Selitrennikoff et al. (US Pat 6743598), teach the use of phosphoglucose isomerase to screen for inhibitors thereof and use of the identified inhibitor as fungicides. Monk et al (Crit. Rev. Microbiol 1994, 20, 209-223) teach the use of ATPases to screen for inhibitors thereof and use of the identified inhibitor as fungicides.

Furthermore, Lohrke et al. (Molec. Plant-Microbe interc. 11 April 2002, 15, 817-825) teach biocontrol of fungi by blocking ribose phosphate isomerase in fungi.

As such it would have been obvious to one of ordinary skill in the art to use the ribose phosphate isomerase taught by Lohrke et al. (Molec. Plant-Microbe interc. 11

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April 2002, 15, 817-825) or Sorensen et al.(J. Bacterol. Feb 1996, 1003-1011) to screen for chemical inhibitors thereof as suggested by Selitrennikolf et al. (US Pat 6743598 or Monk et al (Crit Rev. Microbiol 1994, 20, 209-223) with the expectation that inhibitors identified by the method would be useful as fungicides.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mohammad Meah whose telephone number is 571-272-1261. The examiner can normally be reached on 8:30-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).




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Examiner, Art Unit 1652

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